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10/530,087	01/30/2006	Chad Munro	8932.1091-999	7522

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/530,087

Applicant(s)

MUNRO ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 12/27/2006.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the bone plate and the medullary pin are one piece must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheets should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 4 is objected to because of the following informalities: the claim states, "...has a further transverse borehole...". The examiner believes the claim should state, "...the distal half of the intramedullary pin further includes a transverse borehole..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11, 13, 15, 16, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

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Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation “an angle β of between 0 degrees and +100 degrees”, and the claim also recites “and preferably of between +40 degrees and +50 degrees” which is the narrower statement of the range/limitation.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation “an angle β of between 0 degrees and –100 degrees, and the claim also recites “preferably of between –40 degrees and –50 degrees” which is the narrower statement of the range/limitation.

8. Claim 2 states, “and a center of gravity, if projected onto a cross-sectional area orthogonal to the longitudinal axis of the medullary pin, lies on a radius, which encloses in this cross-sectional area an angle β of between 0 degrees and +100 degrees and

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preferably of between +40 degrees and +50 degrees with the projection of the borehole axis of the proximal transverse borehole". The examiner is unclear if the above portion of claim 2 is limitations for the bone plate. The claim does not clearly state that the projection is a necessary limitation for the invention. For examining purposes, the examiner is going to treat the above portion of claim 2 as functional language and not a limiting characteristic of the bone plate.

9. Claim 3 states, "and a center of gravity, if projected onto a cross-sectional area orthogonal to the longitudinal axis of the medullary pin, lies on a radius, which encloses in this cross-sectional area an angle β of between 0 degrees and -100 degrees and preferably of between -40 degrees and -50 degrees with the projection of the borehole axis of the proximal transverse borehole". The examiner is unclear if the above portion of claim 3 is limitations for the bone plate. The claim does not clearly state that the projection is a necessary limitation for the invention. For examining purposes, the examiner is going to treat the above portion of claim 3 as functional language and not a limiting characteristic of the bone plate.

10. Claim 2 recites the limitation "medullary pin" in 4. There is insufficient antecedent basis for this limitation in the claim. Claims 3-6, 8-11, 13, and 15 have similar antecedent basis problems. The examiner recommends the applicant reviews all the claims for any additional lack of antecedent basis problems.

11. Claim 1 recites the limitation "the pin" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 7, 16, 18, and 20 have similar antecedent

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basis problems. The examiner recommends the applicant reviews all the claims for any additional lack of antecedent basis problems.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 7, 9, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemello (U.S. Patent 6,077,264).

Regarding claim 1, Chemello discloses a device comprising an intramedullary pin and a bone plate. The intramedullary pin includes a longitudinal axis, a proximal end, and a distal tip. The proximal half of the pin includes at least one borehole passing through the pin transverse to the longitudinal axis. The at least one borehole defines a transverse borehole axis. The bone plate is attached to the proximal end of the pin with a length extending towards the distal end of the intramedullary pin and ends proximally above the borehole in the pin. The bone plate is further capable of contacting the greater trochanter during use. Regarding claims 2 and 3, Chemello discloses a device wherein the bone plate as an angled tab with a center of gravity. Regarding claim 7, Chemello discloses a device wherein the bone plate includes an angled tab with a center of gravity, wherein the center of gravity and the transverse borehole axis can be projected onto any cross-sectional area taken orthogonal to the longitudinal axis of the pin, wherein an angle beta between the projection of the center of gravity and the

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projection of the transverse borehole axis is between 40 and 50 degrees. Regarding claim 9, Chemello discloses a device wherein the bone plate has a circular borehole and that the proximal end of the intramedullary pin has a cylindrical elevation corresponding thereto, so that the bone plate may be disposed about the elevation. The plate has a circular borehole for a screw to pass to fix the bone plate to the intramedullary pin. A broad definition of the word cylinder can be, "a solid bounded by a closed generalized cylinder and two parallel planes (mathworld.wolfram.com/Cylinder.html), which does not require the cylinder to be circular. Therefore, the intramedullary pin has a non-circular cylindrical elevation or prism at the proximal end, so that the bone plate may be disposed about the elevation. Regarding claim 13, Chemello discloses a device wherein the tab extends around the medullary pin at an angle between 10 and 200 degrees.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chemello (U.S. Patent 6,077,264).

Regarding claim 6, Chemello discloses the invention as claimed except for the bone plate and the intramedullary pin being one piece. With regard to the bone plate and the intramedullary pin being a unitary structure, it is noted that Chemello discloses

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a device comprising a bone plate and an intramedullary pin that are rigidly secured together as a single unit. Therefore, the constituent parts are so combined as to constitute a unitary whole or structure. In re Larson, 144 USPQ 347 (CCPA 1965).

Regarding claim 16, Chemello discloses the invention as claimed except for the center of gravity and the transverse borehole axis can be projected onto any cross-sectional area taken orthogonal to the longitudinal axis of the pin, wherein an angle beta between the projection of the center of gravity and the projection of the transverse borehole axis is between -40 and -50 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone plate of the device of Chemello wherein an angle beta between the projection of the center of gravity and the projection of the transverse borehole axis is between -40 and -50 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

16. Claims 1-8, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stedtfeld (DE 198 29 228 C1) in view of Chemello (U.S. Patent 6,077,264).

Regarding claim 1, Stedtfeld discloses a device comprising an intramedullary pin. The intramedullary pin includes a longitudinal axis, a proximal end, and a distal tip. The proximal half of the pin includes at least one borehole passing through transverse to the longitudinal axis of the pin and defines a transverse borehole axis. Regarding claim 4, Stedtfeld discloses a device wherein the distal half of the intramedullary pin has a

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transverse borehole passing through the pin. Regarding claim 5, Stedtfeld discloses a device wherein the distal half of the intramedullary pin includes at least two transverse grooves. Regarding claim 8, Stedtfeld discloses a device wherein the proximal half of the intramedullary pin includes a second transverse borehole. Stedtfeld fails to disclose the device further comprising a bone plate attached to the proximal end of the intramedullary pin. Chemello teaches a device includes a bone plate that includes an angled tab and a center of gravity that is attached to the proximal end of an intramedullary pin in order to bring fragments of bone together (column 2 lines 4-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Stedtfeld to further include a bone plate attached to the proximal end of the intramedullary pin in view of Chemello in order to bring fragments of bone together.

Regarding claim 6, the combination of Stedtfeld and Chemello disclose the invention as claimed except for the bone plate and the intramedullary pin being one piece. With regard to the bone plate and the intramedullary pin being a unitary structure, it is noted that the combination Stedtfeld and Chemello disclose a device comprising a bone plate and an intramedullary pin that are rigidly secured together as a single unit. Therefore, the constituent parts are so combined as to constitute a unitary whole or structure. In re Larson, 144 USPQ 347 (CCPA 1965).

Regarding claim 7, the combination of Stedtfeld and Chemello disclose a device wherein the bone plate includes an angled tab with a center of gravity, wherein the center of gravity and the transverse borehole axis can be projected onto any cross-

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sectional area taken orthogonal to the longitudinal axis of the pin, wherein an angle β between the projection of the center of gravity and the projection of the transverse borehole axis is between 40 and 50 degrees. Regarding claim 13, the combination of Stedtfeld and Chemello disclose a device wherein the tab of the bone plate extends about the medullary pin at an angle of about 10 to 200 degrees.

Regarding claim 16, the combination of Stedtfeld and Chemello disclose the invention as claimed except for the center of gravity and the transverse borehole axis can be projected onto any cross-sectional area taken orthogonal to the longitudinal axis of the pin, wherein an angle β between the projection of the center of gravity and the projection of the transverse borehole axis is between -40 and -50 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone plate of the combination of Stedtfeld as modified by Chemello wherein an angle β between the projection of the center of gravity and the projection of the transverse borehole axis is between -40 and -50 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stedtfeld (DE 198 29 228 C1) in view of Chemello (U.S. Patent 6,077,264) further in view of Pennig (U.S. Patent 5,356,410).

Regarding claim 14, the combination of Stedtfeld and Chemello disclose the invention as claimed except for the bone plate having at least one perforation. Pennig

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teaches a device comprising a bone plate attached to an intramedullary pin wherein the bone plate includes at least one perforation in order to allow bone screws to pass through the bone plate and into the bone (column 2 lines 38-46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Stedtfeld modified by Chemello wherein the bone plate includes at least one perforation in view of Pennig in order to allow bone screws to pass through the bone plate and into the bone.

18. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stedtfeld (DE 198 29 228 C1) in view of Chemello (U.S. Patent 6,077,264) further in view of Seidel (U.S. Patent 4,858,602).

Regarding claim 18, the combination of Stedtfeld and Chemello disclose the invention as claimed except for the bone plate having an angled tab with a pair of arms extending toward the distal end of the intramedullary pin. Seidel teaches a device comprising an intramedullary pin and a bone plate, wherein the bone plate includes a plurality of flexible arms in order to support fractured bone segments (column 4 lines 9-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Stedtfeld modified by Chemello wherein the bone plate includes an angled tab with a pair of flexible arms in view of Seidel in order to support fractured bone segments.

19. Claims 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stedtfeld (DE 198 29 228 C1) in view of Chemello (U.S. Patent

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6,077,264) further in view of Seidel (U.S. Patent 4,858,602) further in view of Pennig (U.S. Patent 5,356,410).

Regarding claims 17, 19, and 20, the combination of Stedtfeld, Chemello, and Seidel disclose the device as claimed except for the angled tab of the bone plate to include a plurality of perforations. Pennig teaches a device comprising a bone plate attached to an intramedullary pin wherein the bone plate includes an angled tab with a plurality of perforations in order to allow bone screws to pass through the bone plate and into the bone (column 2 lines 38-46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Stedtfeld modified by Chemello further modified by Seidel wherein the angled tab of the bone plate includes a plurality of perforations in view of Pennig in order to allow bone screws to pass through the bone plate and into the bone.

20. Claims 1-3, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aginsky (U.S. Patent 4,227,518) in view of Chemello (U.S. Patent 6,077,264).

Regarding claim 1, Aginsky discloses a device comprising an intramedullary pin and a bone plate attached to the proximal end of the intramedullary pin. The intramedullary pin includes a proximal end, a distal tip, and a longitudinal axis.

Regarding claims 2 and 3, Aginsky discloses a device wherein the bone plate has an angled tab and a center of gravity. Regarding claim 9, Aginsky discloses a device wherein the bone plate has a circular bore and the proximal end of the intramedullary pin has a cylindrical elevation corresponding thereto, so that the bone plate may be

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disposed about the elevation. Regarding claim 11, Aginsky discloses a device wherein the cylindrical elevation of the intramedullary pin has an external thread. Regarding claim 12, Aginsky discloses a device further comprising a nut with an internal thread corresponding to the external thread of the cylindrical elevation. Aginsky fails to disclose the device having at least one transverse borehole in the proximal half of the intramedullary pin. Chemello teaches a device comprising a bone plate and an intramedullary pin wherein the intramedullary pin has at least one transverse borehole in the proximal half of the intramedullary pin in order to insert a transverse screw through the intramedullary pin (column 4 lines 49-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Aginsky with a transverse borehole in the proximal half of the intramedullary pin in view of Chemello in order to insert a transverse screw through the intramedullary pin.

Response to Arguments

21. Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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